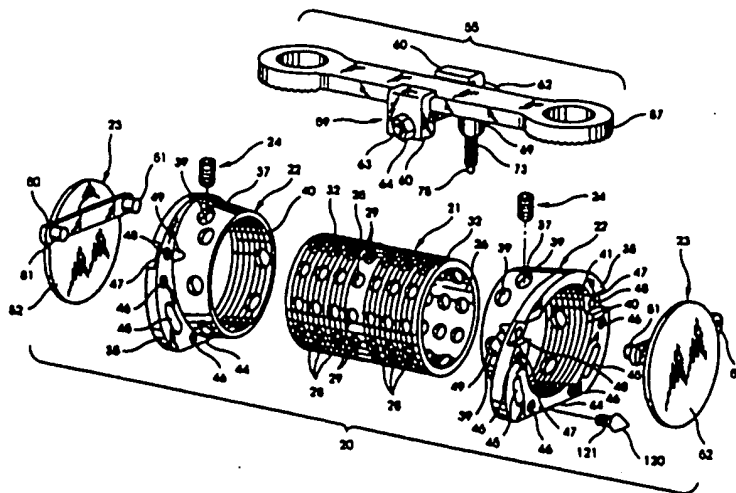




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/44		A1	(11) International Publication Number: WO 96/17564
			(43) International Publication Date: 13 June 1996 (13.06.96)
(21) International Application Number: PCT/US95/15654		(81) Designated States: AU, CA, CN, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 1 December 1995 (01.12.95)			
(30) Priority Data: 08/353,566 9 December 1994 (09.12.94) US		Published With international search report.	
(71) Applicant: SOFAMOR DANEK GROUP, INC. [US/US]; 1800 Pyramid Place, Memphis, TN 38132 (US).			
(72) Inventors: RABBE, Louis-Marie; Route de Dijon, F-70100 Mantoche (FR). BOYD, Lawrence, M.; 5105 Lynbar Avenue, Memphis, TN 38117 (US). CHEVALIER, Jean- Louis; 57, avenue d'Artois, F-62155 Merlimont-Plage (FR). MOREAU, Jean-Charles; Villa La Musarde, Avenue des Canadiens, F-62520 Le Touquet-Paris-Plage (FR).			
(74) Agents: BECK, Michael, D. et al.; Woodard, Emhardt, Naughton, Moriarty & McNen, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).			

(54) Title: ADJUSTABLE VERTEBRAL BODY REPLACEMENT



(57) Abstract

An adjustable vertebral body replacement implant assembly (20) includes a thin-walled cylindrical body (21) configured to span over most of the length between intact vertebrae. The cylindrical body (21) defines a hollow interior (26) with a plurality of bone-ingrowth apertures (28, 29) communicating with the interior. The assembly further includes endplates (22) configured to contact the adjacent vertebrae and to engage the cylindrical body therebetween. The cylindrical body and the endplates include mating threads (32, 40, 41) to permit adjustment of the overall height of the implant. In one embodiment is a set screw (24) for locking the cylindrical body to the endplates. In another embodiment, a crimping channel (100) and notch (101) are defined in the endplates to be crimped onto the cylindrical body. A means for connecting the replacement implant to a longitudinal member is provided, which is one embodiment includes an arm (94) projecting from the endplates with an opening (95) to receive a longitudinal member (105) therethrough.

PN : EP 0797418 A1 971001
 AN : EP 95942527 951201
 PR : US 353566 941209
 NO : WO 9617564 —
 DS : AT BE CH DE DK ES FR GB GR IE IT LI LU MC NL PT SE
 MC : A61F- 02/44
 ET : ADJUSTABLE VERTEBRAL BODY REPLACEMENT
 FT : DISPOSITIF REGLABLE DE REMPLACEMENT D'UN CORPS VERTEBRAL
 GT : ANPASSBARER WIRBELKRPERERSATZ
 PA : SOFAMOR DANER GROUP, INC.
 IN : RABBE, Louis-Marie
 BOYD, Lawrence, M.
 CHEVALIER, Jean-Louis
 MOREAU, Jean-Charles
 ND : ESPACE 97/060 FIRST 97/007
 FIRST 96/004 WORLD 96/044
 AB : An adjustable vertebral body replacement implant assembly (20) includes a thin-walled cylindrical body (21) configured to span over most of the length between intact vertebrae. The cylindrical body (21) defines a hollow interior (26) with a plurality of bone-ingrowth apertures (28, 29) communicating with the interior. The assembly further includes endplates (22) configured to contact the adjacent vertebra and to engage the cylindrical body therebetween. The cylindrical body and the endplates include mating threads (32, 40, 41) to permit adjustment of the overall height of the implant. In one embodiment is a set screw (24) for locking the cylindrical body to the endplates. In another embodiment, a crimping channel (100) and notch (101) are defined in the endplates to be crimped onto the cylindrical body. A means for connecting the replacement implant to a longitudinal member is provided, which is one embodiment contemplates a clamp and screw assembly (55) and another embodiment includes an arm (94) projecting from the endplates with an opening (95) to receive a longitudinal member (105) therethrough.

AF : L'invention concerne un implant réglable (20) prévu pour remplacer un corps vertbral. Cet implant comprend un corps cylindrique (21) parois minces configuré pour recouvrir la plus grande partie de la longueur entre les vertbres intactes. Le corps cylindrique (21) présente un intérieur creux (26) avec une pluralité d'orifices (28, 29) prévus pour la croissance osseuse interne communiquant avec l'intérieur. L'ensemble comprend, en outre, des plaques terminales (22) configurées pour venir au contact des vertbres adjacentes et pour assurer l'insertion du corps cylindrique entre elles. Le corps cylindrique et les plaques terminales comprennent des filetages correspondants (32, 40, 41) pour permettre le réglage de la hauteur globale de l'implant. Dans un mode de réalisation, une vis régulatrice (24) est prévue pour verrouiller le corps cylindrique aux plaques terminales. Dans un autre mode de réalisation, un canal de serrage (100) et une encoche (101) sont définis dans les plaques terminales pour être serrés sur le corps cylindrique. Un moyen pour raccorder l'implant à un lment longitudinal est prévu. Dans un mode de réalisation, ce moyen se compose d'un ensemble dispositif de serrage et vis (55) et dans un autre mode de réalisation, il comprend un bras (94) dépassant des plaques terminales avec un orifice (95) pour y recevoir un lment longitudinal (105).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

ADJUSTABLE VERTEBRAL BODY REPLACEMENT

BACKGROUND OF THE INVENTION

The present invention concerns an implant for replacement of one or more vertebral bodies and their adjacent disks. More particularly, the vertebral body replacement is particularly well suited for implantation through an anterior approach.

The treatment of injuries to the spine has advanced significantly since the days of the first recorded surgical procedure for spinal cord injury in the late 7th Century. The techniques, instrumentation and implants have changed over the years and have been better adapted to address many forms of spinal injury and deformities that can occur due to trauma, disease or congenital effects. One type of spinal deformity, a kyphosis, involves a prolapse of the vertebral column towards the front of the body, often caused by the destruction of the vertebral body itself. This destruction can be in the form of a trauma type injury, such as a fracture or burst injury to the vertebral body, or a non-traumatic deformity caused by a tumor or a degeneration of the bone in the vertebral body.

Treatment of a kyphosis in the thoracic or lumbar spine appears now to be best achieved through an anterior approach, particularly in order to avoid some of the more severe complications associated with support or replacement of a damaged vertebral body. In most treatments of a kyphosis, a high degree of anterior reconstruction of the spine is required, most frequently involving total removal of the damaged vertebral body. In a typical anterior approach, partial or total ablation of the vertebral body and the two

-2-

adjacent vertebral disks is carried out. The remaining space is then distracted to manipulate the spine to its correct orientation.

In many cases, the space is filled with a polymerizable paste or a bone graft which is frequently modeled to give it the shape of the destroyed vertebral body. Frequently, autologous bone, such as that extracted from the ilium, is used to bridge the space. The polymerizable paste can include a PMMA bone cement. Once the cavity remaining after the removal of the original vertebral body has been filled, an osteosynthesis instrument is positioned between the adjacent unaffected vertebrae to prevent any relative movement therebetween. The osteosynthesis device is essential to restabilize the vertebral column, to support the loads to which the thoracic or lumbar spine is exposed, and to enhance the likelihood and quickness of union of the bone graft material with the adjacent vertebral bodies. Once the bone graft and material is sufficiently solid, the osteosynthesis device normally is not subjected to any further mechanical stresses.

A known osteosynthesis device is depicted in U.S. Patent No. 5,108,395 to Jean-Marie Laurain, the disclosure of which is incorporated herein by reference. This system is illustrated in FIGS. 1 and 2 of the present application. Referring first to FIG. 1, it can be seen that a damaged vertebra V_3 includes a destroyed vertebral body C_3 . An interior implant 1 is provided for bridging between the two intact vertebrae V_2 and V_4 to permit removal of the damaged vertebra V_3 and its adjacent disks D_2 and D_3 . The anterior implant 1 includes a pair of clamps 2 which are engaged to the intact vertebral bodies by way of a number of spikes 3. In addition, the clamps 2 are maintained in position by bone screws 5 extending through screw holes 11, lateral lugs 8 of the clamps. The implant 1 also includes plate 6 which is configured to span between the intact

-3-

vertebrae and is strong enough to support the loads generated in the spinal column at that location.

Each clamp 2 includes a threaded post 12 projecting therefrom which is configured to pass through a corresponding opening 14 at each end of the plate 6. A nut 7 is adapted to engage the threaded post 12 to fix the plate 6 to each of the clamps 2. The surface of the clamps 2 include serrations 15 which mate with corresponding serrations 16 at each end of the plate 6, thereby permitting differing angular orientations of the plate relative to each of the clamps. An opening 9 is provided through the threaded post 12 of the clamps to receive another bone screw 5 for firm fixation of the clamp with the healthy vertebral bodies V_2 and V_4 .

An important feature of the system described in the '395 patent is the provision of notches 18 in each of the clamps 2. The notches are configured to receive the tips of a forceps 19 which is used to provide a distraction force between the two vertebrae V_2 and V_4 . As shown in FIG. 2, once the clamps 2 are fixed to the corresponding intact vertebrae, the forceps 19 are used to distract and permit room for placement of a bone graft G. Once the bone graft is in place, the anterior plate 6 can be attached to each of the clamps 2 in the manner previously described. Once the plate is in position, the distraction forceps 19 is removed and the nut 7 tightened to form a rigid construct.

The anterior construct shown in the '395 patent and in FIGS. 1 and 2 of this application is one system for providing anterior fixation with the use of autologous or allogenic bone graft material. Other implants have been devised which rely upon an additional element interposed between the adjacent vertebra, in lieu of or in addition to the traditional bone graft material. One such device is shown in the patent to Harms et al. no. 4,820,305, which is sold as the "Harms Cage" by the Biedermann-Motech Company. This device contemplates a hollow cylindrical mesh which is

-4-

inserted in the gap between adjacent vertebra, with bone graft material being disposed inside the hollow interior of the mesh.

The patent to Brantigan, No. 5,192,327, shows a device
5 similar to the "Harms Cage" which is composed of a number of hollow oval-shaped implants within which bone graft material is disposed. European Patent No. 0 179 695 to Kehr shows a rigid inert body having a number of passageways extending
between the intact vertebrae into which bone growth material
10 can be implanted. In addition, the device shown in the Kehr European patent includes a plate spanning between the vertebrae having holes for receiving bone screws therethrough.

Another variety of implant devices particularly suited
15 for replacement of vertebral bodies include components of generally solid construction which completely occupy the empty vertebral space. These devices are represented by the patents to Kapp et al., no. 4,554,914; Doty, no. 4,599,086; Ogilvie et al., no. 4,636,217; and Downey, no. 5,147,404.
20 Each of these devices is provided with a spike or similar mechanism for engaging the end plates of the intact vertebra to maintain the implant in position. A similar construction is followed in the U.S. Patent 5,062,850 to MacMillan et al. although this device includes open space between support
25 columns of the axially fixed vertebral body prosthesis.

In each of the former patents, the implant device requires separate distraction of the intact vertebrae prior to insertion of the device. The following patents show vertebral prosthesis which include some feature for expansio
30 of the device *in situ*. For example, the Main et al., no. 4,932,975, and Barber no. 5,236,460 show prostheses that telescope through the admission of a hydraulic fluid. The patents of Rezaian, no. 4,401,112; Wu, no. 4,553,273 and Daher, no. 4,657,550 show devices that expand *in situ* the
35 manipulation of a threaded component. In addition, the

-5-

Rezaian patent shows a turnbuckle construct of this type with the addition of a spiked plate engaged in the opposite intact vertebrae to strengthen the construct.

In recent years, the application of anterior approaches
5 to instrumenting the spine has become more prevalent. As these anterior approaches advance, it becomes of greater necessity to provide a vertebral body replacement that meets all of the benefits of anterior surgery without the
10 detriments of the several prior devices. Each of the above-mentioned vertebral body replacements suffer from one or more disadvantages. For instance, some of the devices do not provide means for osteosynthesis between the intact vertebrae. These devices lack features that can either
15 permit bone ingrowth or facilitate placement of bone graft between adjacent healthy vertebrae. It is recognized that a more permanent and stable correction of a kyphotic condition occurs with fusion of a bony mass in place of the replaced vertebra. Thus, any vertebral body replacement should
20 accommodate this aspect. Other vertebral prosthesis offer no means for adjusting the size of the implant to accommodate the specific vertebral anatomy. Further, other of the devices do not contemplate some auxiliary fixation to help provide a stable construct. Each of these needs, and many others, are met by the vertebral body replacement according
25 to the present invention.

SUMMARY OF INVENTION

The present invention contemplates a vertebral replacement implant and assembly for fixation of the implant in the space left by a removed vertebra between two intact vertebrae. In one aspect, the implant includes a thin-wall cylindrical body sized to occupy a substantial portion of the space between the intact vertebrae. The cylindrical body is hollow with a plurality of apertures through the wall of the body in communication with the interior, to permit bone ingrowth once the implant is implanted. The opposite ends of the cylindrical body carries continuous threads, preferably on the outer surface of the body.

The inventive implant further contemplates a pair of endplates having a surface directed against a corresponding one of the intact vertebrae when the prosthesis is implanted. The endplates each include a cylindrical portion extending from the end surface, which portion includes threads for mating with the threaded ends of the cylindrical body. Preferably, the threads of the endplates are internal to the cylindrical portion. In one aspect, the endplates are themselves hollow to provide communication between the hollow interior of the cylindrical body and the adjacent intact vertebrae. Alternatively, the invention contemplates the addition of an end cap to the implant to close the end surface of the endplates against the adjacent vertebrae in order to provide additional support for weak vertebrae.

Another feature of the invention resides in the provision of means for fixing the cylindrical body to each of the endplates to prevent unthreading of the mating threads of the three components of the implant. In one embodiment, the means for fixing includes apertures in the threaded portion of the endplates which are threaded to accept a set screw. Preferably, two set screws are threaded into two such apertures in the endplates to apply a clamping pressure

-7-

against the cylindrical body engaged with the endplate.

In another embodiment, the means for fixing contemplates a crimpable cylindrical portion of the endplates. In one aspect, the cylindrical portion includes an annular ring, 5 dissected by a crimping notch. The application of a crimping force around the annular ring reduces the notch, and thereby reduces the circumference of the cylindrical portion so it is tightly engaged about the cylindrical body threaded therein.

Another inventive aspect resides in the provision of 10 means for connecting the implant to a longitudinal member extending outside the space left by the removed vertebrae. The longitudinal member may be a plate or a rod that is fixed in a known manner to the adjacent intact vertebrae. Preferably, the longitudinal member can be used to assist in 15 the distraction of the intact vertebrae for insertion of the vertebral replacement implant.

In one embodiment, the means for connecting includes a clamp configured to clamp onto the longitudinal member. The clamp supports a screw directed towards the replacement 20 implant when it is interposed between the intact vertebrae. The cylindrical body of the implant includes a number of apertures threaded to receive the connecting screw. The clamp is preferably slidable along the length of the longitudinal implant to facilitate alignment of the screw 25 with the number of threaded apertures of the cylindrical body. In addition, the clamp includes a spherical seat, and the screw includes a spherical head to permit varying angular orientations of the screw relative to the longitudinal member.

In another embodiment, the means for connecting includes 30 an arm extending from a flange of the endplates. The free end of the arm defines an opening through which the longitudinal member extends. A set screw intersects the opening to provide fixation of the longitudinal member to the arm of the endplates.

35 One object of the present invention is to provide a

-8-

vertebral body replacement implant configured to support the space left by removal of a damaged or diseased vertebra. Or objective is to provide an implant that can be easily adjusted to vary the overall length of the implant dependent
5 upon the vertebral level into which the implant is interposed. A further objective of the inventive implant is to permit this length adjustment yet provide means for fixing the components to prevent disengagement or unthreading.

A further object is achieved by the present invention by
10 the provision of means for connecting the vertebral replacement implant to a longitudinal member extending along the length of the spine between the adjacent intact vertebrae. The longitudinal member can be used for distracting the space left by the removed vertebra to
15 facilitate insertion of the replacement implant. Yet another object is to provide an implant that can house bone growth material to facilitate fusion of the instrumented level.

One benefit of the vertebral body replacement of the present invention is that it provides a strong implant to
20 support the spinal loads while awaiting fusion of bone growth material between the intact vertebrae. A further benefit is that the implant can be more easily adjusted to accommodate spaces at different vertebral levels.

Other objects and benefits of the invention can be
25 gleaned from the following written description of the invention, considered together with the accompanying figure and claims.

DESCRIPTION OF THE FIGURES

FIG. 1 is an exploded perspective view of a spinal osteosynthesis implant according to the prior art patent 5,108,395.

5 FIG. 2 is a view showing a portion of the view of FIG. 1 with the addition of an instrument for permitting positioning of a graft between the vertebrae carrying the clamps associated with the prior device of the '395 patent.

10 FIG. 3 is an exploded perspective view of a vertebral body replacement assembly in accordance with one embodiment of the present invention.

FIG. 4 is an end elevational view of an endplate used in connection with the vertebral body replacement assembly shown in FIG. 3.

15 FIG. 5 is a side elevational view of an endplate used with the vertebral body replacement assembly of FIG. 3.

FIG. 6 is a perspective exploded view showing a component of the clamp assembly used with the vertebral body replacement assembly shown in FIG. 3.

20 FIG. 7 is a side elevational view of a vertebral body replacement assembly in accordance with another embodiment of the invention, particularly for use with an elongated rod spanning the vertebral sections.

25 FIG. 8 is an end elevational view of the vertebral body replacement assembly shown in FIG. 7, with the assembly shown in position on a intact vertebra.

FIG. 9 is a side elevational view of the assembly shown in FIG. 7 as engaged to an elongated rod.

30 FIG. 10 is a perspective view of the endplate used with the vertebral body replacement assembly shown in FIG. 7.

FIG. 11 is an end elevational view of one specific endplate used in connection with the vertebral body replacement assembly shown in FIG. 3 in the thoracic spine.

-10-

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to FIG. 3, a vertebral body replacement assembly 20 is shown in accordance with one embodiment of the present invention. The assembly 20 generally includes a threaded cylindrical body 21, threaded endplates 22 and end caps 23. A set screw 24 is also provided as one embodiment of a means for fixing each of the endplates 22 to a corresponding end of the cylindrical body 21. In one specific embodiment, the set screw 24 is a breakable locking screw in which the head of the screw shears off when the tightening torque limit is reached. Such a locking screw is disclosed in co-pending French patent application No. 94 10 377, filed on August 29, 1994.

The threaded cylindrical body 21 is formed from a cylindrical wall 25 which defines a hollow cavity 26 therein. The cavity is configured to receive bone osteosynthesis material, which may be in the form of autogenous or allograft material. The cylindrical wall 25 is provided with a plurality of apertures 28 in communication with the cavity 26. These apertures provide a path for bone or tissue ingrowth to further enhance the stability of the implant. The cylindrical wall 25 includes a second plurality of threaded apertures 29 generally in the middle of the

-11-

implant, which are configured to engage the support assembly 55 as described in more detail herein.

In one important feature of the cylindrical body 21, the opposite ends of the cylindrical wall 25 are formed into external threads 32. In one specific embodiment, the threads 32 extend from each opposite end over most of the total length of the threaded cylindrical body 21 and are configured to engage the threaded endplates 22. Each endplate includes a flange 35, which preferably assumes a shape to cover a substantial load-bearing area of the end plates of the adjacent intact vertebral bodies. A cylinder 37 is integrally formed with flange 35 to extend toward the threaded cylindrical body 21 when the endplates 22 are placed within the excised vertebral space. The cylinder 37 of each endplate includes a number of threaded openings 39 adapted to receive a set screw 24 therein.

The cylinder 37 and flange 35 of the endplates 22 define a bore 40 therethrough. The inside surface of the bore 40 is provided with internal threads 41 which are configured to mate with the external threads 32 of the cylindrical body 21. In the preferred embodiment, the threads 41 extend along at least the entire length of the cylinder 37 and preferably into the flange 35.

Further details of the endplates 22 can be seen in FIGS. 4 and 5. As shown in FIG. 5, the cylinder 37 is integrally formed with the flange 35 to define a lordosis angle 43. This angle is intended to permit use of the vertebral body replacement assembly 20 to replace a damaged vertebra, such as vertebra V_3 shown in FIG. 1, and still maintain the normal lordotic curvature of the spine at that level. The end face 36 of the flange 35 is provided with vascularization apertures 45 extending through the flange. These apertures 45 are intended to provide an avenue for vascularization of the space between the adjacent vertebrae. The end face 36 can be provided with four spikes, such as spikes 91 shown in

-12-

the embodiment of FIG. 7. Alternatively, spikes 120 (FIG. 3) can be provided that include a threaded stem 121 to be engaged in threaded apertures 46 defined in end face 36. In either case, the spikes (91, 120) are configured to penetrate the end plate of the adjacent vertebra to help maintain the position of the implant in situ.

The end face is further provided with a mounting slot 47 passing across the flange 35 and spanning along a chord of the internal bore 40. Within each mounting slot is an aperture 48 passing therethrough. The cylinder 37 of the endplate 22 is provided with a mounting notch 49 that is aligned with each aperture 48 in the mounting slot 47. This slot 47, aperture 48 and notch 49 are configured to support an end cap 23, as herein described. Referring back to FIG. 3, the end cap 23 includes a generally rectangular support bar 50 which is mounted to span across a chord of the flat circular plate 52 of the end cap. At each end of the support bar 50 is an outwardly projecting lug 51. Each lug 51 is sized to be received within a corresponding aperture 48, while the support bar 50 is itself configured to fit within the mounting slot 47 in the flange 35. Further, each lug 51 slides conveniently into a corresponding mounting notch 49 in the cylinder 37. In this manner, the end cap 23 is held in position, particularly when the replacement body assembly is disposed between the adjacent intact vertebrae V_2 and V_4 .

The end cap 23 provides additional support for the implant between the adjacent intact vertebrae. The end cap can be eliminated if bone growth between the adjacent vertebrae and through the replacement body is preferred. Alternatively, the plate 52 of each end cap 23 can be perforated to permit bone ingrowth between the vertebral end plates and the bone growth material disposed within the threaded cylindrical body 21. In the preferred embodiment, the endplates are shown solid to provide the maximum load bearing capability for loads along the length of the vertebral column.

-13-

In the illustrated embodiment, the threads 32 on the cylindrical replacement body are external threads, while the threads 40 in the endplates are internal. Alternatively, the cylinder 37 of the endplates can carry external threads and the cylindrical replacement body carry internal threads in the cavity 26. In this latter instance, the inner diameter of the cylindrical body would naturally be slightly greater than the outer diameter of the cylinder of the endplates.

In the preferred embodiment, the cylindrical wall forming the implant 21 can be relatively thin, when compared against replacement bodies of the prior art. In one specific embodiment, the wall is one (1) mm. thick. Since the primary load endured by the implant will be axial compression, rather than bending, a thin-walled cylinder is appropriate and even desirable.

It is also preferred that the implant 21 include a large number of apertures 28, 29 to promote tissue ingrowth and vascularization, thereby enhancing the stability of the construct after fusion has occurred. In one specific embodiment, the total area of the plurality of apertures is at least twenty five percent (25%) of the surface area of the cylindrical body 21.

In use, the damaged vertebra, such as vertebra V_3 shown in FIG. 1, is removed. In one embodiment, the clamps 2 of the interior implant 1 shown in FIGS. 1 and 2 are engaged to the intact vertebral bodies in the manner shown in FIG. 2. Also shown in FIG. 2, the forceps 19 can be used to distract the intact vertebrae to permit implantation of a vertebral body replacement assembly 20. In the preferred method, the optimum vertebral height is determined and the threaded cylindrical body 21 and threaded endplates 22 are fitted together to achieve that proper height. Specifically, each of the end-caps can be threaded onto the threaded cylindrical body 21 until the desired height is attained.

It is important that the bottom edge 44 of the flange 35

-14-

of each of the endplates be generally oriented in the same way between the two threaded endplates 22. This orientation is important because the replacement assembly 20 will be disposed between the two intact vertebrae, bearing against the end plates of those vertebrae. In order to maintain the maximum load bearing capability, the flanges 35, and particularly the end face 36, assume the shape of the vertebral body against which the endplates bear and are size to occupy as much area of the intact vertebral body end plat as possible.

Preferably, three such shapes are provided to accommodate the anatomic variations of the vertebral bodies at the lumbar, thoraco-lumbar and thoracic levels. the configuration of the flange 35 shown in FIG. 4 is applicable to the thoraco-lumbar vertebrae. A smaller, more rounded, configuration can be provided for implantation at the thoracic level, such as the flange 35' shown in FIG. 11. The flange 35' is also shown as including a relief radius 38 to increase the clearance between the flange and the dural space housing the spinal cord. This relief radius 38 is preferably included in all three shapes of the endplate flanges.

In one specific embodiment, the external threads 32 on the threaded cylindrical body 21 are cut in opposite directions so that the endplates can be drawn together or apart by rotating only the cylinder. Thus, as the cylinder is rotated in one direction, the threads 32 at each of the ends engage the internal threads 41 of each of the end caps 23 in the right direction to draw the end caps together. Alternatively, the handedness of the threads 32 can be the same at each end so that it is necessary to individually thread each end cap in opposite directions onto the cylindrical body 21. The disadvantage of this arrangement is that it is more difficult to adjust the height of the total assembly 20 while maintaining the proper orientation of each of the lower edges 41 of the end face 36. An advantage is that *in situ* the assembly is unable to unthread itself.

-15-

Once the endplates and threaded cylindrical body have been engaged in the proper orientation for the correct height, the set screws 24 are threaded into an appropriate one of the threaded openings 39 in the cylinder 37 of the endplates 22, in order that the set screw 24 extend into contact with the threaded cylindrical body 21. The set screws 24 (which can be the breakable locking screws mentioned above) exert a clamping pressure against the body 21 to hold it in place. Thus, the set screws 24 provide a means for fixing the components together and prevent rotation of the cylindrical body 21 with respect to either of the endplates 22. Preferably, two set screws are used at each endplate 23 to firmly fix the associated ends of the threaded cylindrical body 21. To ensure that the set screws 24 achieve firm purchase on the body 21, the apertures 28 in the threaded body have a smaller diameter than the set screws 24.

With the cylinder and endplates thus fixed at their proper height dimension, bone graft material can then be inserted into the bore 40 of the endplates and cavity 26 of the cylindrical body 21. After the interior of these components has been completely filled with bone graft material, the endplates 23 are placed in position with the lugs 51 extending through apertures 48, and with support bar 50 passing through mounting slot 47 in each endplate. The replacement assembly 20 can then be disposed between the distracted vertebrae V_2 and V_4 . Once the assembly is properly positioned with the end faces 36 of each of the endplates 22 properly oriented on the vertebral end plates, the distraction forceps 19 are removed so that the assembly 20 is clamped in place between the two vertebrae.

In order to further ensure that the replacement assembly 20 will not migrate or slip in its position between the intact vertebrae, a support assembly 55 may be provided. In the preferred embodiment, this support assembly 55 is configured to mate with the clamps 2 used with the anterior

-16-

implant system of the prior art shown in FIGS. 1 and 2. The support assembly 55 can also be used with other anterior plates, such as the Z-PLATE ATL* sold by Danek Medical, Inc., or rod systems such as the CD Hopf System of Sofamor, S.N.C.

In particular, the support assembly includes a stabilization plate 57, which can be configured substantially similar to the plate 6 shown in FIG. 1, including the serrations on the bottom face of the ends of the plate.

Means for connecting the vertebral replacement body assembly 20 to the plate 57 includes a clamp assembly 59 is provided which firmly grips the plate 57 to support a locking screw 69. The clamp assembly 59 includes a pair of clamp halves 60 which are preferably in the shape of a C to grip and support the plate 57. Each of the clamp halves 60 include an aperture (not shown) which receives a threaded rod 63 of an adjustment plate 62. A nut 64 is threaded on the rod 63 to draw the clamp halves 60 together about the stabilization plate 57.

The details of the adjustment plate 62 are shown more clearly in FIG. 6. The adjustment plate includes the threaded rod 63 extending from a face 65 of the plate 62. The plate 62 also includes an aperture 67 therethrough having a spherical seat surface 68 into which a corresponding spherical head 70 of the locking screw 69 is received. The locking screw 69 includes a hex recess 71 in its head to accept a driving tool. The locking screw 69 also includes a threaded shank 73 which is adapted to engage one of the threaded apertures 29 in the threaded cylindrical body 21.

To help guide the locking screw 69 into position, a guide nub 75 is provided having a smaller diameter than the threaded shank 73. The locking screw 69 preferably includes smooth shank 74 between the head 70 of the screw and the threaded shank 73.

In use, the clamp halves 60 can be tentatively attached

-17-

but not clamped to the stabilization plate 57. The stabilization plate 57 can then be engaged to the clamps 2 in each of the intact vertebral bodies and fixed in place by a corresponding nut, such as nut 7 shown in FIG. 1. With the stabilization plate 57 thus attached between the distracted vertebrae, the distraction forceps 19 can be removed so that the full load of the spinal column can be borne by the replacement assembly 20. Once the distraction forceps have been removed, the clamp halves 60 can be adjusted along the length of the plate 57 so that the locking screw 69 is aligned with an appropriate one of the threaded apertures 29 in the threaded cylindrical body 21. The spherical contact between the head 70 of the locking screw 69 and the spherical seat 68 of the adjustment plate 62 allows the locking screw to assume whatever angle is necessary to engage a threaded aperture 29. As so aligned, the locking screw 69 can then be easily threaded into one of the apertures 29 until it is locked between the adjustment plate 62 and the threaded cylindrical body 21. At this point then, the clamp halves 60 can be fully clamped onto the plate 57 by tightening the nut 64 on the threaded rod 63.

In another embodiment of the invention, a vertebral body replacement assembly 80 is configured for connection to an elongated distraction or compression rod. In this embodiment, the assembly 80 includes opposite endplates 83 which are configured to threadedly engage a cylindrical body 21. (This cylindrical body 21 is substantially identical in all respects to the cylindrical body 21 described with respect to FIG. 3). With this embodiment, the endplates 83 include a flange 85 and a cylinder 87 projecting therefrom. The cylinder 87 includes a threaded bore 88 which is threaded to accept the external threads 32 of the cylindrical body 21. Like the prior endplates, the endplate 83 includes a plurality of vascularization apertures 89 formed through the flange 85. The end face 86 of the flange 85 includes a

-18-

number of spikes 91 projecting therefrom. The spikes are configured to penetrate the end plate of the adjacent vertebral bodies to help maintain the position of the impla *in situ*.

5 As shown in FIGS. 7 and 8, the endplates 83 include an arm 94 projecting from the flange 85, which is a component a means for connecting the implant to a longitudinal member such as rod 105. A rod bore 95 is defined adjacent the free end 94a of the arm 94, with a set screw bore 96 intersecting
10 the rod bore 95 from the free end of the arm 94. A set screw 98 is provided which is engaged within the set screw bore 96 to clamp a rod passing therethrough.

The manner of using the replacement assembly 80 in this embodiment is shown in FIGS. 8 and 9. In particular, the
15 endplates 83 are engaged in the appropriate vertebrae by way of spikes 91. Again, the plates are configured to define an angle 115 to correspond to the proper spinal anatomy at the particular vertebral level. A distraction plate 107 is mounted into each of the intact vertebrae by way of bone
20 screw 108. The plate 107 includes a collar 109 integrally formed thereon through which a distraction rod 105 passes. The distraction rod also extends through each of the rod bores 95 in the arms 94 of the endplates 83. With the rod extending through each of the bores, the set screws 98 fix
25 the endplates in position. Distraction of the adjacent vertebrae can be achieved by an appropriately formed instrument that can engage the collars 109 of each of the distraction plates 107 mounted into the respective vertebrae. A set screw (not shown) can be provided to fix
30 the rod 105 within each collar 109.

Referring to FIGS. 7, 9 and 10, details of the manner which the endplates are fixed to the threaded cylindrical body is described. In particular, the endplates 83, and particularly the cylinder 87 of the endplates, is provided
35 with a means for fixing in the form of a crimping channel

-19-

100 around the diameter of the cylinder. At opposite sides of the cylinder, a crimping notch 101 is provided in the channel 100. In essence, this crimping notch is a gap in the outer circumference of the channel 100. This crimping notch
5 provides a gap which can be closed by an appropriate crimping tool gripping the entire circumference of the crimping channel 100. As the crimping tool is tightened, the notches 101 close as the channel moves together in the direction of the arrows 102. It can be seen that this crimping aspect
10 will replace the set screw 24 disclosed with the previous embodiment for fixing the endplates to the threaded cylindrical body.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is
15 to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

2/7

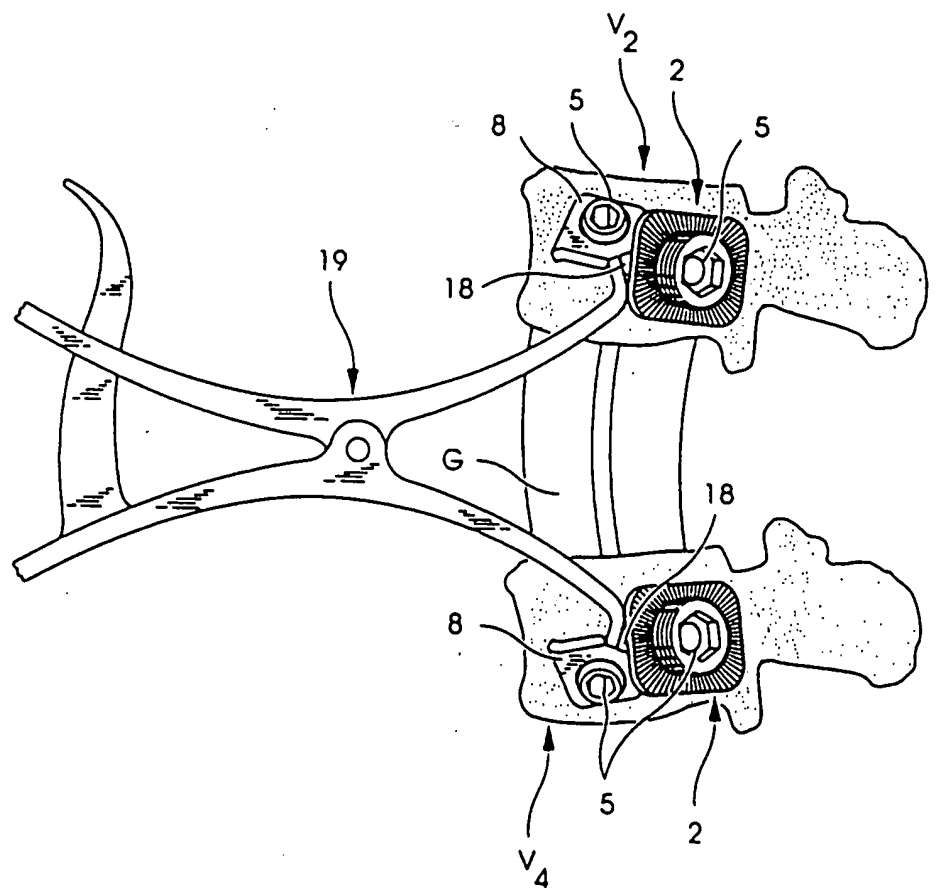


Fig. 2
(PRIOR ART)

-20-

What is claimed is:

1. A vertebral replacement implant for interposition in a space left by one or more removed vertebrae between adjacent intact vertebrae, comprising:

5 a replacement body with opposite ends sized to span a portion of the space between the intact vertebrae, said replacement body having first threads defined thereon at each of said opposite ends; and

a pair of endplates each having an end surface for
10 contacting a respective one of the intact vertebrae when the implant is interposed in the space, each of said endplates having a cylindrical portion integrally extending from said end surface, said cylindrical portion having second threads defined thereon configured to threadedly engage the first
15 threads on said replacement body, each of said endplates further defining a bore therethrough opening at said end surface and at said cylindrical portion.

2. The vertebral replacement implant according to claim 1, wherein said replacement body includes a cylindrical wall
20 defining a hollow interior, said cylindrical wall defining a plurality of apertures therethrough, said apertures being in communication with said hollow interior of said replacement body to facilitate tissue ingrowth into said replacement body.

3. The vertebral replacement body according to claim 2
25 wherein said cylindrical wall defining said replacement body has a surface area and said plurality of apertures define an effective area greater than twenty five percent (25%) of said surface area.

4. The vertebral replacement implant according to claim
30 2, wherein the hollow interior of said replacement body is open at said opposite ends.

-21-

5. The vertebral replacement implant according to claim 1, wherein said replacement body includes a cylindrical wall defining a hollow interior and is open at said opposite ends.

6. The vertebral replacement implant according to claim 5, wherein each of said endplates defines a bore therethrough opening at said end surface and at said cylindrical portion.

7. The vertebral replacement implant according to claim 6, wherein said first threads on said replacement body are external threads and said second threads on said cylindrical portion of said pair of endplates are internal threads.

8. The vertebral replacement implant according to claim 1, further comprising an end cap for closing said bore of one of said endplates at said end surface thereof, said end cap having means for supporting the end cap on the endplate.

9. The vertebral replacement implant according to claim 1, wherein said first threads on said replacement body are external threads and said second threads on said cylindrical portion of said pair of endplates are internal threads.

10. The vertebral replacement implant according to claim 1, further comprising means for fixing said replacement body to each of said endplates to prevent unthreading of said first and second threads.

11. The vertebral replacement implant according to claim 10, wherein said means for fixing includes:

a number of openings defined in said cylindrical portion of each of said pair of endplates; and

a member extendable through one of said number of apertures into contact with said replacement body.

-22-

12. The vertebral replacement implant according to claim 11, wherein:

said member is a set screw; and

said number of openings is threaded to receive said set screw in threaded engagement.

13. The vertebral replacement implant according to claim 11, wherein said number of openings are defined in said endplates at said second threads.

14. The vertebral replacement implant according to claim 1, wherein each of said endplates includes a flange defining said end surface, said flange extending radially outwardly from said cylindrical portion and defining a shape generally corresponding to the shape of a portion of the intact vertebra against which the endplate is in contact.

15. The vertebral replacement implant according to claim 14, wherein said flange defines a number of vascularization apertures therethrough.

16. The vertebral replacement implant according to claim 15, wherein:

said end cap includes;

a plate shaped to correspond to said bore opening said endplate; and

a support bar attached to said plate; and

said endplate includes a slot defined at said end surface for receiving said support bar so that said plate of said end cap resides flush with said end surface of said endplate.

17. The vertebral replacement implant according to claim 10, wherein:

said cylindrical portion of each of said endplates has

-23-

length projecting from said end surface; and

said means for fixing includes a crimping notch formed along a portion of said length of said cylindrical portion, said cylindrical portion being deformable at said crimping
5 notch to close said notch and thereby reduce the circumference of said cylindrical portion about said replacement body when said body is threadedly engaged to said endplate cylindrical portion.

18. The vertebral replacement implant according to claim
10 1, wherein each of said pair of endplates includes a number of spikes projecting from said end surface for implantation in a corresponding one of the adjacent intact vertebrae.

19. The vertebral replacement implant according to claim
18, wherein:

15 said end surface of each of said pair of endplates defines a number of threaded apertures therein; and each of said number of spikes includes a threaded post configured for engagement with said threaded apertures in said end surface of each of said endplates.

20 20. The vertebral replacement implant according to claim 1, wherein said cylindrical portion of each of said endplates extends from said end surface at a non-perpendicular angle, said angle corresponding to the curvature of the spine at the space left by the removed vertebra.

25 21. The vertebral replacement implant according to claim 1, wherein each of said endplates includes a flange defining said end surface and extending outwardly from said cylindrical portion, said flange including an arm projecting away from said cylindrical portion, said arm having a free
30 end configured to extend beyond the adjacent intact vertebrae for engagement to a longitudinal member disposed along the length of the spinal column.

-24-

22. The vertebral replacement implant according to claim 21, wherein said arm defines a bore at said free end for receiving the longitudinal member therethrough.

23. An assembly for fixation of adjacent intact
5 vertebrae following removal of an intermediate damaged vertebra, comprising:

a vertebral replacement implant including;

a replacement body with opposite ends sized to span a portion of a space left by the removal of the damaged
10 vertebra, said replacement body having first threads defined thereon; and

a pair of endplates each having an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, each of said
15 endplates having a cylindrical portion integrally extending from said end surface, said cylindrical portion having second threads defined thereon configured to threadedly engage the threads on said replacement body
an elongated longitudinal member sized to span between
20 and fixedly engage the adjacent intact vertebrae outside the space left by the removal of the damaged vertebra; and
means for connecting said vertebral replacement implant to said longitudinal member.

24. The assembly for fixation of adjacent intact
25 vertebrae according to claim 23, wherein:

said replacement body defines a number of threaded openings; and

said means for connecting includes:

a clamp for clamping said longitudinal member; and
30 a screw attached to said clamp, said screw having threads for engaging one of said number of threaded openings and having a length sufficient for said screw to engage said replacement body when said clamp is engaged to said longitudinal member.

-25-

25. The assembly for fixation of adjacent intact vertebrae according to claim 24, wherein:

said clamp includes a plate, said plate defining an aperture having a spherical seat; and

5 said screw includes a spherical head configured for engagement within said spherical seat.

26. The assembly for fixation of adjacent intact vertebrae according to claim 22, wherein:

10 each of said endplates includes a flange defining said end surface and extending outwardly from said cylindrical portion; and

15 said means for connecting includes an arm integral with said flange and projecting away from said cylindrical portion, said arm having a free end configured to extend beyond the adjacent intact vertebrae for engagement to the longitudinal member.

27. The assembly for fixation of adjacent intact vertebrae according to claim 26, wherein:

20 said arm defines a first bore at said free end for receiving the longitudinal member therethrough and a set screw bore at said free end intersecting said first bore; and

25 said means for connecting includes a set screw for threading into said set screw bore, said set screw having a tip for engaging a longitudinal member extending through said first bore.

28. A vertebral replacement implant for interposition in the space left by a removed vertebra between adjacent intact vertebrae, comprising:

30 a replacement body with opposite ends and having a length sized to span a portion of the space between the intact vertebrae;

-26-

a pair of endplates each having an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, each of said endplates having an engagement portion integrally extending from said end surface; and

means between said opposite ends of said replacement body and said engagement portion of each of said endplates for engaging said endplates to said replacement body at variable positions along the length of said replacement body.

29. The vertebral replacement implant according to claim 28, wherein said means for engaging includes mating threads defined on said opposite ends of said replacement body and each of said endplate engagement portions.

30. The vertebral replacement implant according to claim 28, further comprising means for fixing said replacement body to each of said endplates to prevent disengagement of said means for engaging.

31. A vertebral replacement implant for interposition in the space left by a removed vertebra between two intact vertebrae, comprising:

a thin-walled cylindrical body defining a hollow interior, the wall of the cylindrical body defining a plurality of apertures having a combined area at least equal to twenty-five percent (25%) of the outer surface area of the body, said body having opposite ends with continuous threads formed at each of said opposite ends; and

a pair of endplates, each endplate formed by a flange defining an end surface for contacting a respective one of the intact vertebrae when the implant is interposed in the space, and each endplate further including a cylindrical portion integrally projecting from said flange, said cylindrical portion defining a continuous thread for

-27-

engagement with the threads at the opposite ends of said thin-walled cylindrical body, each of said endplates defining a bore therethrough to communicate with the hollow interior of said thin-walled cylindrical body when said body is
5 threadedly engaged with the endplate.

32. The vertebral replacement implant according to claim 31, wherein:

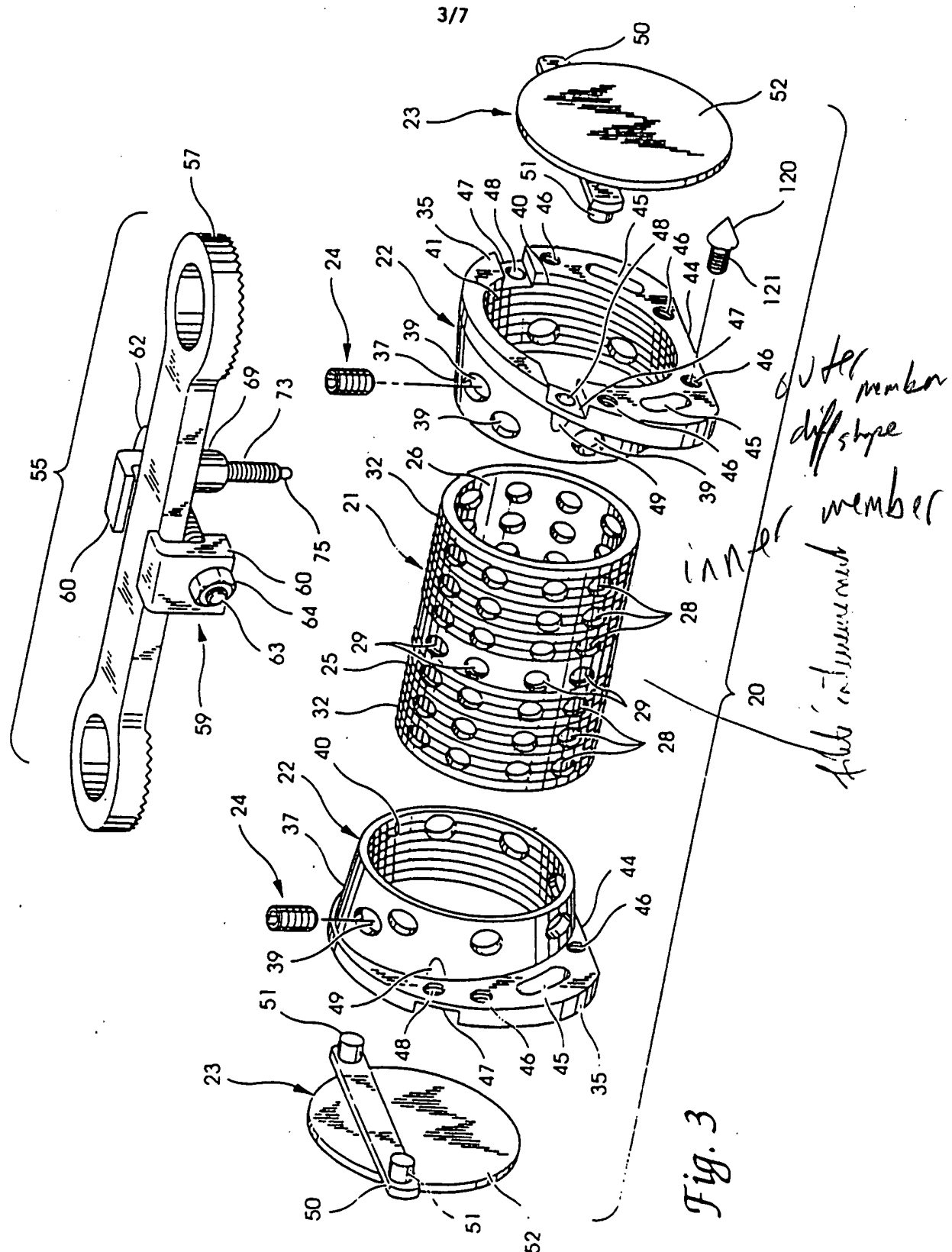
said cylindrical portion of each of said endplates has a length projecting from said end surface; and

10 said cylindrical portion defines a crimping notch formed along a portion of said length of said cylindrical portion, said cylindrical portion being deformable at said crimping notch to close said notch and thereby reduce the circumference of said cylindrical portion about said
15 cylindrical body when said body is threadedly engaged to said endplate cylindrical portion.

33. The vertebral replacement implant according to claim 2, wherein some of said plurality of apertures extend through said first threads of said replacement body.

20 34. The vertebral replacement implant according to claim 7, wherein said replacement body includes a cylindrical wall defining a hollow interior, said cylindrical wall defining a plurality of apertures therethrough, said apertures being in communication with said hollow interior of said replacement
25 body to facilitate tissue ingrowth into said replacement body.

35. The vertebral replacement implant according to claim 34, wherein some of said plurality of apertures extend through said external threads of said replacement body.



4/7

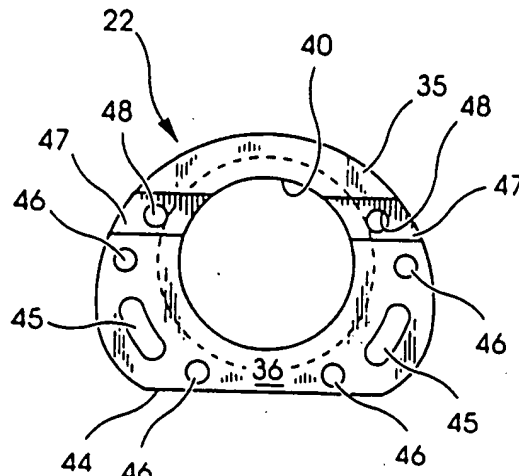


Fig. 4

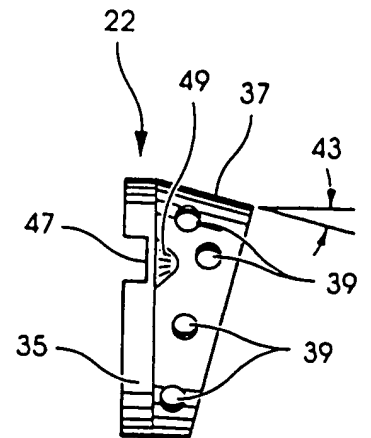


Fig. 5

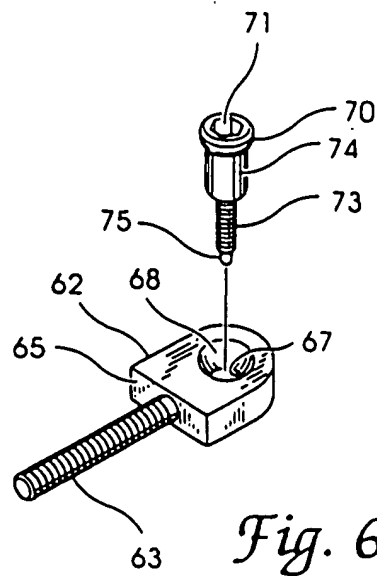


Fig. 6

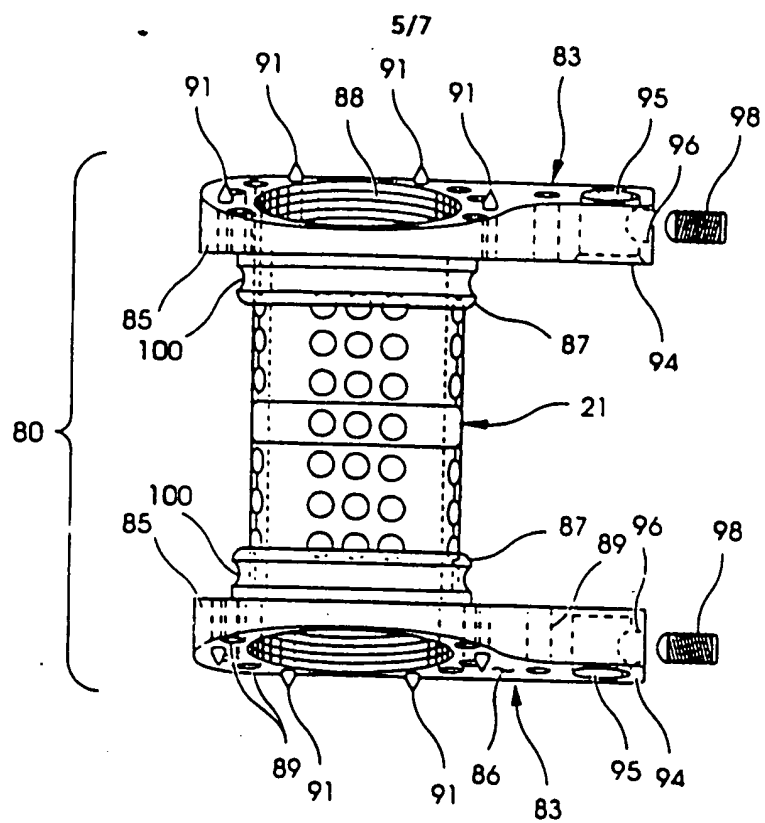


Fig. 7

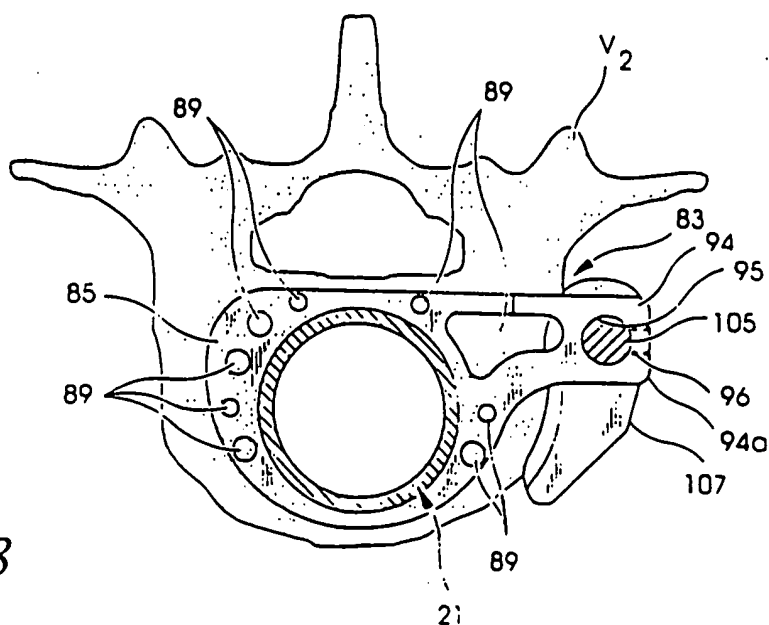
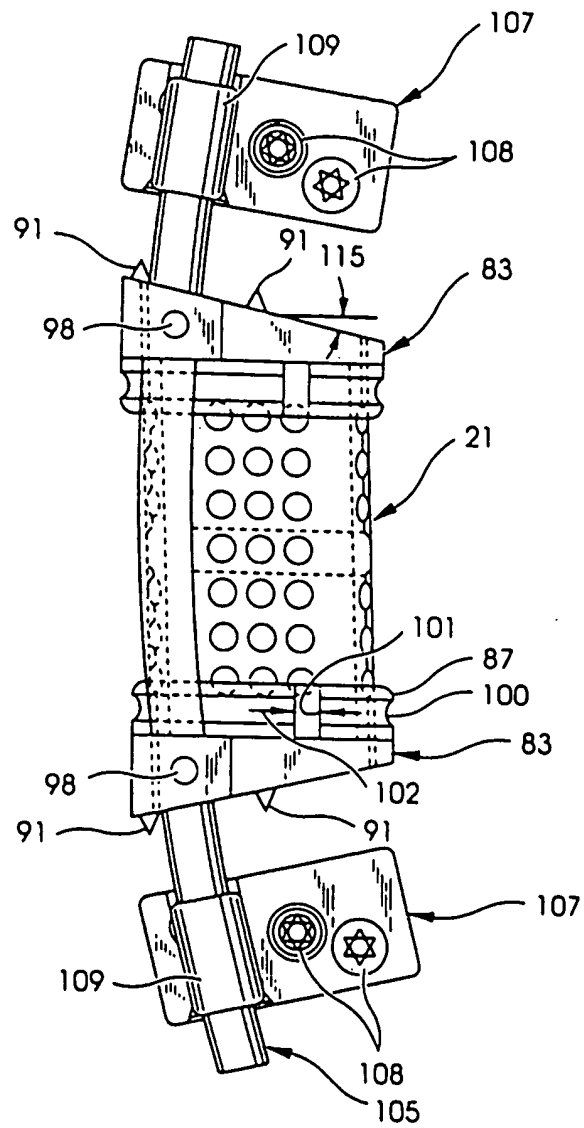


Fig. 8

6/7

*Fig. 9*

7/7

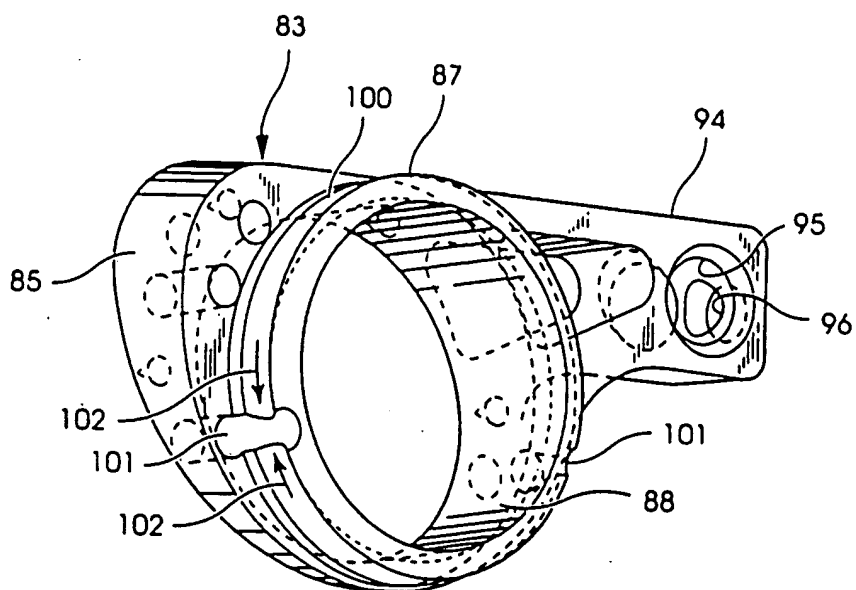


Fig. 10

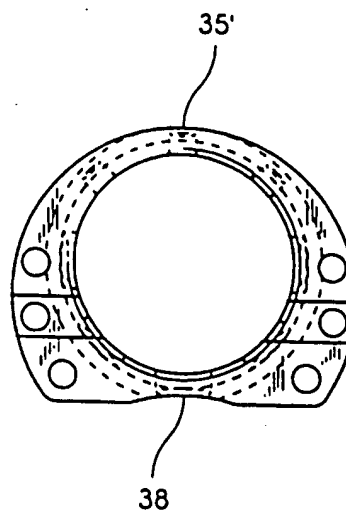


Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/15654

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/44

US CL : 623/17

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/61, 71; 623/17, 22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	EP, A, 567424 (APARICI ET AL.) 27 October 1993, entire document.	1, 2, 4-6, 10-12, 14, 28-30, 33, 34 ----- 3, 7-9, 13, 15, 17-20
Y	US, A, 5,019,108 (BERTIN ET AL.) 28 May 1991, see entire document.	8
Y	US, A, 4,911,718 (LEE) 27 March 1990, see entire document.	15
Y	US, A, 4,553,273 (WU) 19 November 1985, see entire document.	7, 9, 13

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Special categories of cited documents:	
A document defining the general state of the art which is not considered to be part of particular relevance	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
E earlier document published on or after the international filing date	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
L document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another claim or other special reason (as specified)	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
O document referring to an oral disclosure, use, exhibition or other means	*Z* document member of the same patent family
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

05 FEBRUARY 1996

Date of mailing of the international search report

14 MAR 1996

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

MICHAEL MILANO

Telephone No. (703) 308-2496

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/15654

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US. A. 4,657,550 (DAHER) 14 April 1987, see entire document.	17-19
Y	Scientific Rationale, TITANIUM-MESH-CYLINDER, MOSS, July 1989, (J. HARMS ET AL.), pp. 106309 and 106312.	3, 31